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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,179	06/29/2000	Yuan Chang	45185-CA/JPW/SHS	1263

7590 03/22/2004

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/607,179	CHANG ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/18/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 14 (claims 52 and 53, with respect to SEQ ID NO: 14) in the response filed December 18, 2003 is acknowledged. The traversal is on the ground(s) that: (a) the inventions are not independent of each other because there is a disclosed relationship between the different sequences; (b) that a search of multiple sequences would not be burdensome to the Office. This is not found persuasive because of the following reasons:

1. Applicant accurately indicates that inventions are considered independent if they are unconnected in design, operation, and effect. In the instant case, the claimed polypeptides meet each of those qualification in that: (i) they have a distinct design (each consisting of a distinct amino acid sequence); (ii) they have different operations, in that each polypeptide performs a distinct function, which is directly related to the design of the claimed polypeptide; and (iii) they have different effects, in that each polypeptide functions towards a distinct effect. Thus, contrary to Applicant's allegation, the inventions are independent of each other.

2. It was adequately established in the Election/Restriction that the Commissioner considers a search of more than one sequence burdensome. The fact that SEQ ID NO: 14 (of Group 14) has a distinct sequence from those of SEQ ID NO: 2-13 and 15-37 clearly indicates that a sequence that is identical to SEQ ID NO: 2 would not be identical to SEQ ID NO: 14. Thus, one would necessarily have to search each of the multiple sequences, which has been established as burdensome by the Commissioner.

In conclusion, Applicant has not sufficiently established that the restricted inventions are commensurate in scope, or that a search of each of the multiple sequences claimed would not be burdensome. The requirement is still deemed proper and is therefore made FINAL.

Claims 52 and 53 are under examination in the instant application with respect to the elected sequence, SEQ ID NO: 14.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated polypeptide, encoded by at least a portion of SEQ ID NO: 14 (i.e., a fragment of a polypeptide encoded by SEQ ID NO: 14), that uniquely defines a herpesvirus associated with Karposi's Sarcoma. The claims read on a broad genus of peptide fragments which may or may not define a herpesvirus associated with Karposi's Sarcoma.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between

function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a fragment of a polypeptide that uniquely defines a herpesvirus associated with Karposi's Sarcoma by function only, without any disclosed or known correlation between the elements and their function. The specification provides teachings regarding the full-length protein that is encoded by SEQ ID NO: 14, but the specification does not teach which regions of the polypeptide are unique to a herpesvirus associated with Karposi's Sarcoma. Applicant simply presumes that any fragment of the polypeptide encoded by SEQ ID NO: 14 can serve as an identifying polypeptide for such a herpesvirus, simply because SEQ ID NO: 14 is uniquely associated with such a herpesvirus. However, SEQ ID NO: 14 encodes a polypeptide that is 581 amino acids in length; the claims read on any di-amino acid sequence (or higher) within this sequence, each of which must only identify a herpesvirus specifically associated with Karposi's Sarcoma. The specification does not provide any guidance as to which sequences would be necessarily and selectively associated with Karposi's Sarcoma. While it is clear that SEQ ID NO: 14 encodes a protein that appears to uniquely define a herpesvirus associated with Karposi's Sarcoma, the skilled artisan cannot envision a sufficient number of polypeptide fragments within the full length protein (that uniquely define the herpesvirus) from the instant specification because the specification does not describe these polypeptides. As a result, the instant specification does not meet the Written Description requirement for the claimed genus of polypeptides.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of polypeptide fragments encoded by a portion of SEQ ID NO: 14, wherein the encoded polypeptides necessarily and selectively define a herpesvirus associated with Karposi's Sarcoma. Because there is no such disclosure of the relevant structural or functional features of polypeptide fragments encoded by a portion of SEQ ID NO: 14, one of skill in the art could not envision the claimed invention.

Neither the specification of the instant application or the prior art teaches a structure-function relationship for a representative number of polypeptide fragments encoded by a portion of SEQ ID NO: 14, wherein the encoded polypeptides *necessarily and selectively* define a herpesvirus associated with Karposi's Sarcoma. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length SEQ ID NO: 14, does not reasonably provide enablement for the portions of the polypeptide (i.e., fragments) that uniquely define a herpesvirus associated with Karposi's Sarcoma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is any polypeptide fragment encoded by a portion of SEQ ID NO: 14, wherein said polypeptide fragment necessarily and selectively defines a herpesvirus that is associated with Karposi's Sarcoma. In particular, such polypeptides can be used to generate antibodies, which can then be used as diagnostic tools for identifying the herpesvirus in (potentially) infected patients.

Scope of the invention. The scope of the invention is very broad, encompassing any sized fragment found within by the 581 amino acid protein encoded by SEQ ID NO: 14. This includes di-peptides, tri-peptides, etc. However, it is unclear which of these peptides n*ecessarily and selectively* defines a herpesvirus that is associated with Karposi's Sarcoma.

State of the art and Level of skill in the art. The state of the art is silent with regard to which peptide fragments encoded by portions of SEQ ID NO: 14 *necessarily and selectively* define a herpesvirus that is associated with Karposi's Sarcoma. However, the state of the art clearly identifies proteins that are not encoded by SEQ ID NO: 14, many of which may (or may not) contain peptides that *are* encoded by *portions* of SEQ ID NO: 14. These polypeptides could not uniquely define a herpesvirus associated with Karposi's Sarcoma, since they also can be used to

define another protein. Because it is unclear which portions of SEQ ID NO: 14 encode peptides that are also encoded in other proteins, it is unpredictable which of these peptides encoded by portions of SEQ ID NO: 14 uniquely define a herpesvirus associated with Karposi's Sarcoma. Additionally, there are a number of proteins from organisms/viruses that have not been sequenced/identified. Because these proteins are unknown, the skilled artisan could not predict if a particular peptide encoded by a portion of SEQ ID NO: 14 actually did *uniquely define* a herpesvirus associated with Karposi's Sarcoma, because that polypeptide might be present in another protein that is not associated with a herpesvirus or Karposi's Sarcoma. As a result, the skilled artisan would turn to the instant specification for guidance on making and using the claimed invention.

Number of working examples and Guidance provided by applicant. The instant specification only defines the full-length protein that is encoded by SEQ ID NO: 14, which appears to uniquely define the herpesvirus characterized in the instant specification. However, there is no dissection of the protein, whereby the fragments of said protein (i.e., those portions encoded by a portion of SEQ DI NO: 14) that also *uniquely* define the herpesvirus are clearly taught. Without a teaching of which peptide fragments encoded by portions of SEQ ID NO: 14 are absolutely unique to a herpesvirus associated with Karposi's Sarcoma, the skilled artisan could not make or use the claimed invention.

Unpredictability of the art and Amount of experimentation required. The instant claims require a great deal of empirical, undue and unpredictable trial and error experimentation for the full scope of the claims to be enabled. The skilled artisan would need to empirically determine each polypeptide encoded by SEQ ID NO: 14, and then determine which of these polypeptides

are not present in *any* of the other known proteins. Even if the polypeptide is found once, it cannot be considered to uniquely define a herpesvirus associated with Karposi's Sarcoma. Furthermore, the polypeptide must still be unique in the face of other unknown proteins. In the instance where a polypeptide as encoded by a portion of SEQ ID NO: 14 also encodes an unknown protein (or portion thereof), the polypeptide no longer meets the functional limitation of being unique to a herpesvirus associated with Karposi's Sarcoma. Because the skilled artisan cannot predict any of these instances without an undue amount of trial and error experimentation, the full scope of the claims is not enabled.

In conclusion, it certainly appears that the full-length protein encoded by SEQ ID NO: 14 uniquely defines a herpesvirus associated with Karposi's Sarcoma. However, there are no teachings in either the prior art or in the instant specification which defines the regions of the polypeptide that are not present in any other protein, both known and unknown. As a result, the skilled artisan would have to perform trial and error experimentation of an undue nature, to effectively define the broad scope of the claimed invention. As a result, the broad scope cannot be considered enabled, because it cannot be made (and therefore cannot be used) without a burdensome amount of trial and error experimentation.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER